

Remarks

Claims 11-26 and 31-34 were pending in the subject application. By this Amendment, claims 11-26 have been cancelled and new claims 35-37 have been added. Accordingly, claims 31-37 are currently before the Examiner. Favorable consideration of the claims now presented is respectfully requested.

The claim cancellations and presentation of new claims have been done to lend greater clarity to the claimed subject matter and to expedite prosecution. The cancellation of certain claims should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited. The undersigned avers that no new matter is introduced by this amendment.

As an initial matter, the applicant wishes to thank Examiner Mathew and Primary Examiner Brown for the courtesy extended to the undersigned during the personal Examiner Interview conducted on June 6, 2005. This response and the amendments set forth herein are submitted in accordance with the substance of the interview and constitute a summary of that interview. Specifically, in order to expedite prosecution, the applicant has focused the claims on his unique and advantageous method that unexpectedly promotes wound healing.

As discussed in the recent Examiner interview, the device and method of the subject invention advantageously promote the healing of wounds by providing a warm and moist environment with adequate oxygenation and prevention of gross contamination, while capturing potentially voluminous wound exudates with a fluid-absorbent material. The subject invention allows natural exudates from the wound to carry material away from the affected site and be deposited at the fluid absorbent material, thus encouraging wound healing. Further, by allowing exudates to drain away from the wound, the present invention encourages active growth factors and reduces the level of proteinases thereby supporting the wound healing process, while preventing excoriation of unaffected skin. The ability to promote wound healing using the method described and claimed by the current applicant is an important new contribution to the wound care art. As

discussed below, the cited references, alone or in combination, do not disclose or suggest the applicant's advantageous method.

Claims 11-13, 21-23, 25 and 26 have been rejected under 35 U.S.C. §102(b) as being anticipated by Baxter (U.S. Patent No. 4,178,924). In view of the cancellation of these claims, the applicant respectfully submits that this rejection has been rendered moot.

Claims 31-33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Baxter alone. The applicant respectfully traverses this ground for rejection because the Baxter (1979) reference does not disclose or suggest the applicant's advantageous method.

The 1979 Baxter patent for a "cast protector" focuses on maintaining the integrity of a conventional plaster cast. Anybody who has had a cast on a broken leg can appreciate that, if the cast is exposed to water (during bathing, for example), the integrity of the cast is quickly compromised. With this in mind, Baxter provides a waterproof protective cover, the primary purpose of which is to keep water from coming into the device from the outside. The Baxter device is also said to address an additional nuisance – moisture from the skin that causes humidity within the device.

At column 1 lines 15-21, Baxter defines the problem to be addressed as follows:

Most previously designed covers of this type have been subject to leakage of one type or another and have not included adequate means for ventilating and/or absorbing body perspiration with the result that near 100% humidity conditions may often exist within a protective cover resulting in slow softening of the cast material as well as discomfort to the wearer of the cover.

Baxter addresses the first part of the problem by providing a water tight covering with an effective seal to keep water out. The device of the current invention is not concerned with keeping water out of the enclosure. Nor does the instant invention pertain in any way to protecting a cast. Rather, the device and method of the subject invention promote an advantageous wound-healing environment by absorbing large amounts of wound exudates produced inside the enclosure.

The Baxter patent also emphasizes the need to reduce humidity that could cause cast softening. Specifically, in order to reduce humidity arising from perspiration, the Baxter device has bands that are:

constructed of resilient material having moisture absorbing properties, or may be constructed of foam rubber impregnated with a moisture absorbing material such as silica gel.

These bands are located at various points between an inner and outer liner of the cast-protector. Holes 26 are located near each band so that moist air can reach the bands. Although the Baxter patent mentions at column 3 lines 8-9 that a "pad" at the bottom of the device could be made from "substantially the same material" as the aforementioned bands, there is no indication that the pad at the bottom of the device is intended to absorb any moisture. In this regard, note, in Figure 2 of Baxter, the lack of any holes 26 near the pad 33. Also note the absence of any reference to the pad 33 in the following passage that appears at column 3 lines 50-58:

Thus, any body moisture developing within the inner tubular member 18 is at least to some degree purged therefrom and absorbed by the absorbent bands 28, 32 and 34. When the cover 16 is not in use it may be positioned so as to cause a circulation of air through the interior of the inner tubular member 18 and outward through the open upper ends of the tubular member 10 and 20 to thereby dry the moisture absorptive bands 28, 32 and 34 prior to the next use of the cover 16.

Thus, it is questionable whether the Baxter element designated 33 could even reduce humidity. Certainly, it is clear that the Baxter device does not possess any means for absorbing the large amounts of liquid exudate that can come from the wounds treated by the device of the current invention. In fact, in the scenario postulated in the outstanding Office Action wherein the Baxter device is used on a leg with a compound fracture, any fluid from that wound would be absorbed by the cast and, unlike in the current case, would not be removed from the area of the wound. If, by some chance, liquid made it to the closed end of the Baxter device, there are no holes for it to reach the pad and, as stated above, it is at least questionable whether the pad could even absorb exudates.

Thus, whereas the applicant's specification recites the use of a "super-absorbent" material in order to remove exudate from the area of a wound, the Baxter patent utilizes a silica gel to simply reduce humidity. This results in the opposite effect that is achieved by the current patent. Where the current claims call for maintaining a warm and moist environment, Baxter specifically attempts to reduce humidity.

The applicants respectfully aver that the purpose of the Baxter device would be, in effect, frustrated if modified in the way needed to arrive at the subject invention. Specifically, if the Baxter device were somehow modified to create a moist environment as required by the current claims, that would defeat Baxter's stated purposes of reducing humidity. The Federal Circuit has held that where the proposed modification would render the cited apparatus "inoperable for its intended purpose[.]" then the cited reference would lack motivation to perform the proposed modification. *In re Gordon.*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Thus, the skilled artisan lacks motivation to make this modification.

The Baxter patent's emphasis on preventing entry of water into the enclosure and maintenance of a dry environment within the enclosure essentially teaches away from the device of the current invention which requires maintaining a moist environment.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicant's disclosure that provides such a teaching, and the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Srock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art. . ." *In re Dow Chemical Co., supra* at 1531. (emphasis added) In the current case, there would be no reason to modify the Baxter

teachings to arrive at the current invention, nor is there any suggestion in Baxter that the applicant's method would promote wound healing. Accordingly, reconsideration and withdrawal of this rejection under 35 USC §103(a) is respectfully requested.

Claims 15-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Baxter in view of Liman (U.S. Patent No. 3,741,203). In view of the cancellation of these claims, the applicant respectfully submits that this rejection has been rendered moot.

Claims 14 and 34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Baxter in view of Shuler (U.S. Patent No. U.S. 2,690,415). Claim 14 has been cancelled herein, rendering moot this ground of rejection as it pertains to that claim. The applicant respectfully traverses this ground for rejection as it applies to claim 34. The shortcomings of the Baxter reference have been discussed above. The Shuler patent does not cure, or even address, these shortcomings. The Shuler reference does not teach, either expressly or impliedly, a device that provides a warm and moist environment to promote the healing of a wound. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claims 19 and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Baxter in view of Shuler, and further in view of Liman. In view of the cancellation of these claims, the applicant respectfully submits that this rejection has been rendered moot.

Claim 24 has been rejected under 35 U.S.C. §103(a) as obvious over Baxter in view of Augustine (U.S. Patent No. 5,947,914). In view of the cancellation of this claim, the applicant respectfully submits that this rejection has been rendered moot.

In view of the foregoing remarks and the amendment above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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